REMARKS

Reconsideration and allowance of the instant application are respectfully requested.

Claim status

Claims 10-17 are withdrawn from consideration. Claims 1, 4-5, 7-9, 18 and 19 are pending. Claims 2-3 and 6 are cancelled. Claim 20 is new with support from page 17 of the specification.

Obviousness-type Double Patenting Rejection

Again, claims 1, 4-5, 7-9, and 18-19 are provisionally rejected on the grounds of non-statutory obviousness-type double patenting as not being patentable over claims 1-11 of co-pending US application Serial No. 10/588,696.

Applicant acknowledges the rejection and shall file the necessary Terminal Disclaimer to overcome the rejection upon the allowance of claims in the instant application.

§102/103 Rejection

Claims 1, 4-5, 7-9, and 19 are rejected as being anticipated by, or, in the alternative, being obvious over U.S. Patent No. 6,565,782 (hereinafter Wang). Applicant traverses.

As stated in the previous office action, Claim 1 now describes a semipermeable hollow-fibre membrane, particularly for use in hemodialysis, hemodiafiltration and hemofiltration, comprising: a hydrophilic, water-wettable membrane being based on a hydrophobic first polymer selected from the group consisting of an aromatic sulfone polymer, a polycarbonate, polyimide, polyetherimide, polyetherketone, polyphenylene sulfide, or a copolymer or a modification of these polymers, or a mixture of these polymers; and a hydrophilic second polymer selected from the group consisting of polyvinylpyrrolidone, polyethylene glycol, polyvinyl alcohol, polyglycol monoester, polysorbate, carboxymethylcellulose, or a modification or copolymer of these polymers. Claim 1 goes on to describe the semipermeable hollow-fibre membrane as possessing an open-pored, integrally asymmetric structure across its wall with a porous separating layer of thickness 0.1 to 2 µm on its inner surface facing the lumen and an open-pored supporting layer adjoining the separating layer, and having an ultrafiltration rate in albumin solution in the range of 25 to 60 $ml/(h \cdot m^2 \cdot mmHg)$, wherein after prior drying, the hollow-fibre membrane has a minimum sieving coefficient for cytochrome c of 0.8 combined with a maximum sieving coefficient for albumin of 0.005, and whereby the hollow-fibre membrane in the dry state is free from pore-stabilizing additives in the membrane wall.

The Examiner acknowledges that Wang lacks the specific thickness of the separating layer and the ultrafiltration rate in albumin solution, minimum sieving coefficient of cytochrome c and maximum sieving coefficient of albumin. The Examiner then makes a tremendous "leap of faith" by simply asserting that because the membranes described in Wang are made of the same material and are produced by a process which is similar (exactly how "similar" is defined in this instance is not known) as claimed in the instant application, the membranes of Wang inherently possess the same characteristics as the membranes according to the instant invention.

Applicant must first point out that the instant invention relates to hollow fiber membranes. Therefore, the process described by the instant invention is a process by which hollow fibers are produced. This is in contrast to Wang, and more specifically, the examples within Wang which describe a process for manufacturing a flat sheet membrane. Wang simply fails to disclose a process for manufacturing a hollow fiber membrane, contrary to the opinion of the Examiner. Looking to the process described from column 11, line 55 through column 13, line 4, Wang does not disclose a hollow fiber manufacturing process which affords the interior filler being extruded through the central opening of the hollow fiber die, the interior filler

being a coagulation medium for the polymer constituting the membrane structure and which interior filler initiates coagulation and formation of a separating layer on the inner surface of the hollow fiber (see steps c) and d) on page 6 of the instant specification and withdrawn claim 10). Additionally, the ranges with respect to the polymer concentration (sulfone polymer in Wang, synthetic polymer in the instant application) are simply not the same (with the exception of the concentration of 12% by weight). The polymer concentration disclosed in Example 1 of Wang is 9.3%, and thus below the minimum concentration according to the instant application.

To anticipate a claim under 35 U.S.C. §102(b), a single source must contain all of the elements of the claim. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379, 231 USPQ 81, 90 (Fed. Cir. 1986); *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1574, 224 USPQ 409, 411 (Fed. Cir. 1984); *In re Marshall*, 578 F.2d 301, 304, 198 USPQ 344, 346 (C.C.P.A. 1978). Missing elements may not be supplied by the knowledge of one skilled in the art or the disclosure of another reference. *See Structural Rubber Prods. Co. v. Park Rubber Co.*, 749 F.2d 707, 716, 223 USPQ 1264, 1271 (Fed. Cir. 1984). Where a reference discloses less than all of the claimed

elements, an Examiner may only rely on 35 U.S.C. §103. *See Titanium Metals Corp. v. Banner,* 778 F.2d 775, 780, 227 USPQ 773, 777 (Fed. Cir. 1985). Thus, it follows that the processes of Wang and the processes of the instant invention cannot be regarded as being similar, but instead must be regarded as very different from one another.

Taking a closer look at the membranes described by the instant invention and the membranes in Wang, it is important to note that the membranes of the instant invention are membranes for blood purification (Claim 1, preamble) and more specifically membranes suitable for conventional hemodialysis or conventional hemodiafiltration (specification, page 6). In order to function in applications in blood purification addressed by the instant invention (i.e. hemodialysis, hemodiafiltration or hemofiltration) the separating layer of the membranes must possess pore sizes which allow passage of only those blood components which shall be removed during treatment of patients suffering from renal failure. This corresponds to components having a size smaller than albumin as albumin must remain in the blood during blood purification (specification, page 2). Thus, it is necessary to tailor the membrane specifically for the intended use for blood purification. In particular, the separating pore sizes in the separating layer must be of a

certain size so that albumin is unable or essentially unable to pass through the membrane, thus preserving it within the blood. It is essential for the membrane of the instant invention to have a sieving coefficient for albumin of at most 0.005 which means simply that all of the albumin molecules are retained by the membrane and remain in the blood (i.e. no albumin (or nearly so) passes through the membrane wall). Therefore, the membranes according to the instant invention possess pore sizes in the separating layer such that the sieving coefficient for albumin is at most 0.005.

Human albumin has a molecular weight of about 65,000 Dalton. As can be seen from the filtration spectrum (attached hereto), for a molecule having a molecular weight of about 65,000, a pore size of at most 0.02 to 0.03 μm is required in order to allow the membrane to retain the molecule. If the pores in the separation layer are larger than 0.02 to 0.03 μm, the membrane would fail to retain the human albumin as it would instead pass through the membrane wall.

One skilled in the art would note from its title that Wang deals with microfiltration membranes. This is in stark contrast to the membranes disclosed in the instant application which relate to membranes for hemodialysis, hemodiafiltration or

hemofiltration (which, with respect to their separation pore sizes, belong to the category of ultrafiltration membrane, and more specifically are membrane in the lower ultrafiltration range). One skilled in the art would know that for microfiltration, membranes having pore sizes of the separation pores (minimum pore sizes, pore sizes of the pores in the separation layer) in the range of 0.5 to 2 µm are required. As can be seen from the enclosed "Filtration Spectrum", the size of the pores in the separation layer of membranes in the lower ultrafiltration range are by far smaller than the pores of microfiltration membranes.

Wang discloses membranes having a minimum pore size greater than 0.1 µm. (Column 5, Lines 25-28). One skilled in the art would clearly recognize that the membranes disclosed by Wang would lack the ability to retain human albumin resulting in a sieving coefficient for albumin of 1.0. This is several orders of magnitude away from the sieving coefficient for albumin of 0.005 required by claim 1 of the instant invention.

While Wang also addresses application in the area of blood treatment, this relates to applications such as "blood separation protocols, wherein it is desirable to separate the particulate, mostly cellular, fraction of the blood from the

plasma thereof. (column 13, lines 43-45; see also column 13, lines 59-65). Thus, the membranes of Wang can be used for the separation of blood plasma from blood while retaining the blood cells (i.e. the particulate fraction). However, it is well known to one skilled in the art that the blood plasma contains all non-particulate components, which include useful proteins like albumin. Thus, this clearly demonstrates that the membranes of Wang do not possess properties which facilitate their use for blood purification methods such as hemodialysis, hemodiafiltration, or hemofiltration.

It is clearly demonstrated from the reasons stated above that the membranes of the instant invention differ substantially from the membranes disclosed in Wang with regard to their structure, and more specifically, with regard to the size of the pores in the separating layer.

Looking further into the membrane characteristics of the instant invention, Applicant wishes to emphasize once again to the Examiner that the membranes of the instant invention are membranes for blood purification and more specifically membranes suitable for conventional hemodialysis or conventional hemodiafiltration. These applications require certain ultrafiltration rates in order to be able to remove the

necessary proportion of water in blood treatment. (specification, page 10). To accomplish these rates, the membranes of the instant invention show an ultrafiltration rate in albumin in the range of 25 to 60 ml/(h·m^2·mmHg) (see e.g. claim 1). For ultrafiltration rates above 60 ml/(h·m^2·mmHg) a risk exists during dialysis treatment of an extremely low or even negative transmembrane pressure being indicated at the dialysis machine, which may activate the machine's alarm and may further necessitate corrective intervention during treatment.

Looking to Wang, the membranes described therein are highly asymmetric and have a minimum pore size of greater than 0.1 µm in a minimum pore surface and gradually increasing pore sizes throughout the membrane wall to a coarse pored surface having pore sizes up to about 100 µm. (Column 5, Lines 25-30). Simply stated, this means that the membranes of Wang have a rather coarse pored structure which results in high permeability/ ultrafiltration rates for substances such as water.

The membranes described by Wang exhibit such a high permeability for water that they are actually at the upper range obtained by microfiltration membranes. Looking to the membranes in Example 1 of Wang, we see a microfiltration rate for water of 2000 ml/min/9.5 cm^2 at 10 psid. Example 2 illustrates a membrane

having a water flow or ultrafiltration rate for water of 8000 ml/min/9.5 cm^2 at 10 psid. Recalculation of the value given in Example 1 of Wang into the dimension used in the instant application results in a water permeability of 240,000 $ml/(h \cdot m^2 \cdot mmHg)$. Taking into consideration as a first approximation a factor of 10 for the relation between the filtration rate for water and the filtration rate in albumin solution, an ultrafiltration rate in albumin solution of 24,000 $ml/(h \cdot m^2 \cdot mmHg)$ would result for the membranes disclosed in Example 1 of Wang. This exceeds by roughly a factor of 10^3 the ultrafiltration rate in albumin solution according to claim 1 of the instant application which is in the range of 25-60 $ml/(h \cdot m^2 \cdot mmHg)$).

Put simply, Wang discloses microfiltration membranes which, because of their open pored structure, possess membrane properties typically associated with microfiltration membranes, but which are also completely different on a structural level from the properties associated with ultrafiltration membranes or membranes for hemodialysis, hemodiafiltration or hemofiltration with low exchange volumes.

Clearly, as demonstrated above, the membranes of the membranes of Wang do not inherently possess the characteristics

of the membranes required by claim 1 of instant application. The membranes of Wang also differ significantly with respect to the structure when compared to the membranes of the instant application. Applicant also must emphasize that one skilled in the art would not ignore the factual disclosure of Wang with respect to the characteristics of its membranes. Thus, it is improper for one skilled in the art to reach the conclusion that the characteristics of the membranes of the instant application are met by the completely different the membranes disclosed by Wang.

Moreover, looking to Wang as a starting point, it would not be obvious for one skilled in the art to obtain the membranes according to claim 1 of the instant invention simply by discovering the optimum or workable ranges through routine experimentation. Wang fails to come even close to disclosing the general conditions of Applicant's claim 1. Additionally, Wang simply does not disclose membranes for hemodialysis, hemodiafiltration or hemofiltration. Instead, Wang discloses membranes aimed at microfiltration due to the large pore diameters that the membranes possess. Thus, Wang discloses membranes which are diametrically opposed to the membranes of the instant invention. Wang also lacks any reason or motivation for one skilled in the art to modify its teaching in order to

arrive at the membranes taught by the instant invention. Moreover, contrary to the Examiner's assertion, if one skilled in the art attempted to start from Wang and its microfiltration membranes, it would be far from a simple matter to discover the optimal or workable ranges through routine experimentation, but instead requires a great and complex leap in the art to achieve the membranes of the instant invention.

Accordingly, Wang does not disclose all of the elements of claim 1. Thus, clearly claim 1 is neither anticipated nor obvious over Wang and should be allowed. In reference to claims 4-5, 7-9, and 19, "[I]f an independent claim is not anticipated by prior art, then its dependent claims, which necessarily include the limitations of the independent claim, are not anticipated either. *Kovin Assoc. v. Extech/Exterior Technologies*, 2006 U.S. Dist. LEXIS 63250 (N.D. Ill. 2006), citing *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1296 (Fed. Cir. 2002). Thus, claims 4-5, 7-9, and 19 are neither anticipated nor obvious over Wang and should be allowed.

§103 Rejection

Claim 18 stands rejected as being unpatentable over a combination of U.S. Patent No. 6,565,782 (hereinafter Wang) and

U.S. Patent No. 4,604,208 (hereinafter Chu). Applicant traverses.

The above comments regarding Wang are incorporated herein. The prior art reference or combination of references relied upon by the Examiner must teach or suggest all of the limitations of the claims. See *In re Zurko*, 111 F.3d 887, 888-89, 42 U.S.P.Q.2d 1467, 1478 (Fed. Cir. 1997); *In re Wilson*, 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970) ("All words in a claim must be considered in judging the patentability of that claim against the prior art."). The teachings or suggestions, as well as the expectation of success, must come from the prior art, not applicant's disclosure. See *In re Vaeck*, 947 F.2d 488, 493, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991). In this instance, from the information detailed above concerning the shortcomings of Wang, Chu fails to make up for those numerous shortcomings. Hence, it is clear that Wang and Chu fail to teach or suggest all the limitations of Applicant's claims. Thus, claim 18 is not unpatentable over a combination of Wang and Chu and should be allowed.

Conclusion

In view of the foregoing, Applicant requests an early Notice of Allowance.

Respectfully submitted,

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